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| Case Number: | CM15-0135726 | | |
| Date Assigned: | 07/23/2015 | Date of Injury: | 03/10/2008 |
| Decision Date: | 09/18/2015 | UR Denial Date: | 07/09/2015 |
| Priority: | Standard | Application Received: | 07/14/2015 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 28 year old female who sustained an industrial injury on 3/10/08. The mechanism of injury was unclear. She is currently complaining of numbness, tingling radicular pain in right and left arm and weakness; headache. Her pain level was 6/10. On physical exam there was pain in the area of the right trapezius and supraspinatus muscles with spasm; point tenderness of mid-thoracic spinous process with generalized myofascial pain and point tenderness with parathoracic spinal musculature facet capsules; neck exam revealed pain to palpation with spasm; thoracic exam revealed pain to palpation. Medications were Senna, ondansetron, Nucynta, nortriptyline, Colace, albuterol. She had a urine drug screen on 2/25/15 which was normal. Diagnoses include carpal tunnel syndrome; possible subtle disk annular disruption syndrome; lateral epicondylitis; cervical spondylosis without myelopathy; status post radiofrequency neurotomy (9/22/10). Treatments to date include medications with benefit; ice which was helpful; radiofrequency neurolysis of medial branch nerves bilaterally (9/1/12) with 80% improvement of cervical spine pain, headaches and bilateral and upper extremity resolution. Diagnostics include MRI of the cervical spine (6/9/08) showing decreased hydration at C2, 3, 4, 5; electromyography/ nerve conduction study (4/22/09) normal; cervical MRI (9/16/09) was unremarkable; cervical MRI (11/9/09) normal; MRI right shoulder and brachial plexus (12/23/11,12/29/11) unremarkable. In the progress note dated 6/24/15 the treating provider's plan of care includes requests for Senna 8.6 mg; ondansetron 4 mg as needed for nausea; Nucynta 50 mg; nortriptyline 25 mg; Colace 250 mg.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Senna 8.6mg 2 tablets: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Opioid-induced constipation treatment.

Decision rationale: Senna (sennoside) is a laxative. This patient is undergoing treatment with an opioid. The length of time this patient has been on the opioid is unknown. Opioids can commonly cause constipation and treatment to prevent constipation is recommended. ODG states that first line treatment should include physical activity, appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber and some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Uptodate states "Patients who respond poorly to fiber, or who do not tolerate it, may require laxatives other than bulk forming agents." Additionally, "There is little evidence to support the use of surfactant agents in chronic constipation. Stool softeners such as docusate sodium (eg, Colace) are intended to lower the surface tension of stool, thereby allowing water to more easily enter the stool. Although these agents have few side effects, they are less effective than other laxatives." The treating physician did document that he encouraged the patient drink 8 tall glasses of water daily and exercise as tolerated and consume a high fiber diet. However, the treating physician did not report how compliant the patient was to the first line constipation treatment and did not indicate if fiber treatment was initiated. Additionally, no quantitative or qualitative description of bowel movement frequency/difficulty was provided either pre or post-constipation treatment education by the physician, which is important to understand if first line constipation treatment was successful. As such, the request is not medically necessary at this time.

Ondansetron 4mg 1-2 tablets every six hours as needed: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea).

Decision rationale: Ondansetron (Zofran) is an anti-emetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of anti-emetic for nausea and vomiting secondary to chronic opioid use. Additionally, "This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and

radiation treatment. It is also FDA-approved for postoperative use." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. As such, the request is not medically necessary.

Nucynta 50mg 2 tablets twice a day: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: MTUS states regarding the use of opioids that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. The patient subjective pain rating has progressively worsened, indicating that this regimen is not appropriate. There is no total quantity specified. Therefore, the request is not medically necessary.

Colace 250mg twice a day: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Opioid-induced constipation.

Decision rationale: Docusate is a stool softener. This patient is undergoing treatment with an opioid. Opioids can commonly cause constipation and treatment to prevent constipation is recommended. ODG states that first line treatment should include physical activity, appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber and some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Uptodate states "Patients who respond poorly to fiber, or who do not tolerate it, may require laxatives other than bulk forming agents." Additionally, "There is little evidence to support the use of surfactant agents in chronic constipation. Stool softeners such as docusate sodium (eg, Colace) are intended to lower the surface tension of stool, thereby allowing water to more easily enter the stool. Although these agents have few side effects, they are less effective than other laxatives." The treating physician does not document what first line treatments have been tried and what the results of those treatments are. Additionally, no quantitative or qualitative description of bowel movement frequency/difficulty was provided either pre

or post-consipation treatment education by the physician, which is important to understand if first line constipation treatment was successful. As such, the request is not medically necessary at this time.

Nortriptyline 25mg three tablets at bedtime: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines chronic pain Page(s): 13. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, TCA's.

Decision rationale: MTUS states that "Nortriptyline is a tricyclic antidepressant. Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated." ODG states "Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. (Additional side effects are listed below for each specific drug.) It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken." ODG states "Dosing Information: Amitriptyline: Neuropathic pain: The starting dose may be as low as 10-25 mg at night, with increases of 10-25 mg once or twice a week up to 100 mg/day. (ICSI, 2007) The lowest effective dose should be used (Dworkin, 2007)." The treating physician has not provided evidence of improved pain control, improved function and sleep quality from the medication. Additionally, no quantity is given in the request. Therefore, the request is not medically necessary.